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(54) Dolorimeter Apparatus

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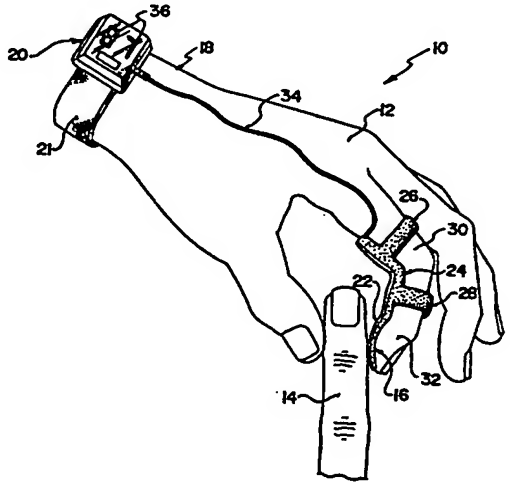

(57) Abstract

A dolorimeter apparatus comprises a member (16) having a property which varies according to pressure applied to the member. A device (26, 28) is provided for securing the member to a hand of a user so the member fits under a finger tip (30, 32) of the user. The member is dimensioned to fit between the finger (30) and body tissue (14) touched by the user while permitting substantial tactile communication to the finger. A device (20) is provided for detecting and quantifying the variance in said property from said member.

* See back of page

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A dolorimeter apparatus comprising:

(a) a member having an electrical property which varies according to pressure applied to the member, the member comprising a pressure sensitive flexible film dimensioned to fit between a finger tip and body tissue to be touched by the user, the member being sufficiently thin and flexible to permit substantial tactile communication between said finger and the body tissue to enable the user to monitor manually the application and location of force applied to the body tissue,

(b) means for securing the member to a hand of the user so said member fits under the finger tip of the user, and

(c) means connected to the member for quantifying the variance in said property outputted from said member.

2. An apparatus as claimed in Claim 1, wherein the film is on a flexible substrate.

3. An apparatus as claimed in Claim 1, wherein said property is electrical resistance of the film.

4. An apparatus as claimed in Claim 1, wherein said property is capacitance.

5. An apparatus as claimed in Claim 1, wherein the means for securing the member includes a band connected to the member, the band having a size to pass around the

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finger.

6. An apparatus as claimed in Claim 1, further including an electrical conductor extending between the member and the means for quantifying the variance in said property outputted from said member.

7. An apparatus as claimed in Claim 1, wherein the means for quantifying the variance in said property of said member includes electronic circuit means for providing a signal representing the pressure applied to the member.

8. An apparatus as claimed in Claim 7, wherein said electronic circuit means includes means for tracking said signal and for holding automatically said signal in a state representing a highest value of pressure applied to the member.

9. An apparatus as claimed in Claim 8, wherein the means for tracking and holding is reset when said signal crosses a threshold value.

10. An apparatus as claimed in Claim 8, wherein said electronic circuit means includes an output device for indicating pressure applied to the member.

11. An apparatus as claimed in Claim 10, wherein said output device includes a digital display.

12. A dolorimeter apparatus, comprising:

(a) a flexible member having electrical resistance which varies with pressure applied to the member, the member comprising a pressure sensitive flexible film dimensioned to fit between a finger tip of a user and body tissue to be touched by

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the user, the member being sufficiently thin and flexible to permit substantial tactile communication between said finger and the body tissue to enable the user to monitor manually the application and location of force supplied to the body tissue,

(b) means for securing the member under the finger tip of the user of the apparatus,

(c) means electrically connected to the member for outputting a signal indicating the electrical resistance of the member, and

(d) means for receiving said signal and for displaying a value indicative of said electrical resistance to the member and thereby the pressure applied to the member.

13. An apparatus as claimed in Claim 12, wherein said means for receiving and for displaying includes electronic circuit means for providing a signal representing the pressure applied to the member.

14. An apparatus as claimed in Claim 13, wherein said electronic circuit means includes means for tracking said signal and for holding automatically said signal in a state representing a highest value of pressure applied to the member.

15. An apparatus as claimed in Claim 14, wherein the means for tracking and holding is reset when said signal crosses a threshold value.

16. An apparatus as claimed in Claim 13, wherein the means for receiving and displaying includes an ohmmeter.

17. An apparatus as claimed in Claim 13, wherein the means for receiving and displaying includes a wrist strap so the means for receiving and displaying can be worn on the wrist of the user.

18. An apparatus as claimed in Claim 12, wherein the means for outputting includes electrical wires operatively connected to the member and to the means for receiving and displaying.

19. An apparatus as claimed in Claim 13, wherein the pressure sensitive film is supported on a flexible substrate.

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DOLORIMETER APPARATUS

BACKGROUND OF THE INVENTION

This invention relates to an apparatus for measuring pressure applied to a patient, for example the minimum pressure applied to an arthritic joint which elicits discomfort.

Physicians place an important role on patterns of pain in the diagnosis and management of their patients. Manual palpation is the standard method of examination, but it has a certain drawback, namely that the procedure is subjective and lacks the precision necessary to accurately assess, for example, the degree of inflammation of arthritic patients.

The limitations of manual palpation have been addressed by providing mechanical devices known as dolorimeters, algesimeters or algometers (the terms are used synonymously herein). In the simplest form, a mechanical dolorimeter includes a simple spring loaded probe connected to a gauge. The gauge indicates the deflection of the probe and hence the pressure applied to the probe. In use, the physician presses the probe against the inflamed joint or other portion of the patient's body suffering pain, and applies pressure until the patient feels discomfort. The reading of the gauge is noted, the reading being an objective indication of the degree of inflammation of the joint, for example.

Electronic dolorimeters have been developed, such as disclosed in United States patent No. 4,641,661 to Kalarickal. This device includes an electronic circuit

housed in a hand-held unit. The dolorimeter has a probe with a resistance which varies according to pressure applied to the probe. The hand-held unit is capable of measuring the resistance of the probe and thereby the pressure applied.

Other devices for determining or recording applied pressure, pain sensitivity or the like are disclosed in U.S. Patent 4,144,877 to Frei et al, U.S. Patent No. 4,501,148 to Nicholas, U.S. Patent 4,503,705 to Polchaninoff, U.S. Patent 4,768,521 to Schiffman et al, U.S.S.R. Patent No. 166,999, Federal German Patent No. 230,696 and European Patent No. 158,336 to Wood.

The devices above substitute the finger of the physician with an inanimate probe, or provide relatively thick or relatively hard force sensors. For this reason, they have an inherent drawback in that they remove certain advantages to the physician and the patient inherent in the touch of the physician's finger. The physician's finger is capable of determining with accuracy the precise location on body tissue where the pain threshold is to be assessed. It is not always easy for the physician to press the inanimate probe at precisely the right location because he or she receives no direct tactile feedback from the probe. In addition, there is an impersonal aspect objectionable to some patients associated with the act of being pressed with an inanimate object. Many patients would prefer the more personal contact of a physician's finger. Prior art force sensors which are relatively thick or relatively hard detract from the physician's ability to locate precisely areas for palpation.

SUMMARY OF THE INVENTION

The invention reduces difficulties of the prior art by providing a dolorimeter apparatus which can output

an objective reading of the minimum pressure which causes discomfort, and also provide the beneficial aspects of manual palpation be enabling a physician to locate easily and precisely an area for palpation.

A dolorimeter apparatus of the invention comprises a flexible pressure responsive member having an electrical property which varies with pressure applied to the member. The member comprises a pressure sensitive film dimensioned to fit between a finger tip of a user and body tissue to be touched by the user. The member is sufficiently thin and flexible to permit substantial tactile communication between the finger and the body tissue by permitting the finger tip to determine accurately a precise location on the tissue, and to apply pressure thereto. The invention also comprises securing means for securing the member under the finger tip of the apparatus and detecting means for detecting variance in the electrical property of the member, the detecting means communicating with the member.

Preferably the film is carried on a flexible substrate so that the flexible member has an overall thickness and flexibility which permits bending under normal forces generated during palpation to facilitate navigation over body tissue. Also, preferably the property which varies is electrical resistance of the film.

The apparatus may also include means for quantifying variance of the property of the member and for displaying a value indicative of said property and thereby the pressure applied to the member. The means for quantifying and displaying may include a ohmeter.

BRIEF DESCRIPTION OF THE DRAWING

Fig. 1 is a perspective view showing a dolorimeter apparatus including a pressure responsive member secured

to a finger of a user, a unit mounted on the wrist of the user for receiving a signal from the pressure sensitive member and for displaying indicia representing said pressure and a finger of a patient; and

Figure 2 is an elevation of the pressure sensitive member removed from the finger, showing some detail and one means of fastening the member to the finger,

Fig. 3 is an electronic block diagram of the dolorimeter apparatus.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figures 1 and 2, a dolorimeter apparatus is shown generally at 10 in association with a physician's hand 12 and a finger 14 of a patient. The apparatus has two principal components, namely a flexible pressure responsive member 16 having an electrical property which varies according to pressure applied to the member, and a receiving and display apparatus 20. The member 16 is attached to a physician's index finger 30 and, in this preferred example, the apparatus 20 is mounted on wrist 18 of the physician using a wrist strap 21.

Referring firstly to the pressure responsive member 16, the member includes a pressure sensitive film 22 on a flexible, sheet-like substrate 24. In the preferred embodiment, the film 22 is a shunt-mode force sensing resistor of the type sold by Interlink Electronics of Santa Barbara California, U.S.A. This device has an electrical resistivity which varies according to the pressure applied to the film. The film 22 is mounted on a substrate which may be, for example, a relatively thin elastomeric membrane having contacts printed thereon for contacting the film 22. The member further includes

securing means for securing the member to the physician's hand which comprises a pair of straps or bands 26 and 28 in this embodiment, the bands being shaped to fit about the index finger 30 of the physician. The straps are connected to a proximal portion 27 of the member 16. Ends of the straps can be releasably connected together to form the bands using releasable connecting means such as "Velcro" fasteners 29, Velcro being a trade mark of the Velcro Corporation. When fitted in place, the film 22 is under tip 32 of the index finger. Also the film has an overall size that approximates to a sensitive portion of the finger tip that is used by the physician for manual palpation. It is important that the pressure responsive member interferes negligibly with normal palpation, and thus it must have a thickness and flexibility that will permit the finger tip of the examining physician to navigate the intricacies of tissues being palpated, for example arthritic finger joints, etc. During normal use, the member 16 will bend when pressed by the finger tip against hard tissue which is surrounded by soft tissue, and the bending of the member 16 should have a negligible effect on the output therefrom. The output characteristics of the member 16 should be such that only actually applied pressure, causing compressive deformation of the member 16, should effect the output of the member and merely bending of the member should have a negligible effect on its output.

Referring to Figure 2, the member 16 has a pressure responsive distal portion 31 which is disposed in a generally circular plan form having a diameter 33 of approximately 0.5 inches (1.0 cms) to approximate to size of the finger tip. The member 16 has a plurality of chordally disposed interdigitated conductors extending alternately from arcuate peripheral conductors 35 and 36 disposed on opposite sides thereof. The member 16 has an overall thickness preferably of between 10 - 20 mil 0.254

- 0.508 mms), and a flexibility that permits bending under normal forces generated during manual palpation. Typically, the film 22 of the shunt mode device is printed on a substrate 24 of Mylar (trade mark) having a thickness of between 3 and 7 mil (0.0762 - 0.1778 mms). Force sensing resistors as manufactured by Interlink Electronics are manufactured in accordance with one or more of the following patents. U.S. 4,451,714, U.S. 4,276,538, U.S. 4,314,228 and U.S. 4,301,337. The disclosures of the relevant references are incorporated herein by reference.

The apparatus includes means for outputting a signal representing the property of the member which varies with pressure applied to the member, in this case the resistivity of the film. In this embodiment the means for outputting includes a 2-wire electrical conductor 34 which is connected to the contacts contacting the film 22 at one end and to receiving and display apparatus 20 at the other end.

The receiving and display apparatus in its simplest form can be an ohmeter with digital display 36 on the face thereof for indicating the instantaneous resistance of the film. Such ohmeters are well known and thus an additional description is not provided. The indicia can simply be a numerical representation, for example on a liquid crystal display, of the resistance of the film. Preferably, however, the apparatus 20 includes a circuit for converting the resistance value to a number in units meaningful to the physician indicative of the pressure applied to finger 14, such as psi or new units unique to this instrument.

Referring to Figure 3, in the preferred embodiment the pressure responsive member 16 is connected by the electrical conductor 34 to a resistance-to-voltage converter 40 of the display apparatus shown in broken

outline generally at 20. The resistance-to-voltage converter provides an output voltage signal representing resistance measured at the pressure responsive member and therefore ultimately represents the pressure applied to the member.

The output of the resistance-to-voltage converter is supplied to a peak detector 42. The peak detector monitors the output voltage from the resistance-to-voltage converter. The peak detector provides its own output voltage which tracks the output voltage of the resistance-to-voltage converter until a highest value is attained, at which time the output voltage of the peak detector is held at this highest value. The output voltage from the peak detector is supplied to an analog-to-digital converter 44 where it is converted into a digital format. The digital format is supplied to an output device such as a digital display 36 which displays data representing pressure applied at the pressure responsive member. Thus, the electronic circuit has means for tracking said signal and for automatically holding said signal in a state representing a highest value of pressure applied to the member.

The display device has two modes of operation, one in which the device is manually reset and a second in which the device is automatically reset. In the manual reset mode, a simple switch 47 is provided to reset the peak detector 42 after a pressure measurement is taken. To use the device in this mode, a physician applies pressure to a patient's finger through the pressure responsive member 16. As the physician gradually increases pressure on the finger, the output voltage of the resistance-to-voltage converter 40 is monitored by the peak detector 42 and pressure values are seen to increase at the digital display 36. At the onset of pain indicated by the patient, the physician may release the pressure

from the finger, and thus also from the member 16, at which time the peak detector 42 will retain at its output the voltage representing the highest pressure inflicted or, in other words, the pain threshold of the patient. The pain threshold pressure value will be displayed on the digital display 46. The display 46 will continue to indicate this pressure value until the physician actuates the manual reset switch thereby resetting the peak detector 42. Resetting the peak detector 42 sets the display 46 back to zero. The apparatus is thus rendered ready to take another pressure measurement.

An analog comparator 48 and a pulse generator 50 are incorporated into the circuit for the automatic reset capability. In the automatic reset mode, the output of the resistance-to-voltage converter is supplied to the analog comparator 48. The comparator compares this voltage with a threshold voltage level and causes the output of the comparator to change the state of its output when the threshold level is exceeded. The output of the comparator is connected to the pulse generator 50 which detects the change in state of the comparator and generates a pulse of short duration. The pulse is supplied to the peak detector 42 and serves to reset the peak detector when the voltage from the resistance-to-voltage converter crosses the threshold level at the comparator. Typically, the threshold level at the comparator is set to an amount lower than the minimum voltage output of the resistance-to-voltage converter for a minimum pressure reading taken by the physician.

In operation, in the automatic reset mode, the physician gradually applies pressure to the finger of the patient through the member 16, thereby changing the resistance of the pressure responsive member and causing the output of the resistance-to-voltage converter 40 to increase. Upon application of minimal pressure, the

output voltage of the resistance-to-voltage converter 40 exceeds the threshold voltage level at the comparator and causes the comparator output to change state. This change of state is detected by the pulse generator 50 which resets the peak detector 42. The peak detector 42 is thus rendered ready to track and monitor the output of the resistance-to-voltage converter. The digital display 46 continuously displays the changing output voltage of the peak detector as the pressure on the patient's finger is increased.

At the onset of pain indicated by the patient, the physician releases the pressure on the patient's finger and the peak detector maintains its output voltage at a value representing the greatest pressure applied to the patient. A numerical value representing this pressure is indicated in appropriate units and maintained on the display even after the physician has released the pressure on the patient's finger. The numerical value will continue to be displayed until pressure is again applied to the pressure responsive member which generates a voltage above the threshold level to reset the peak detector. It may readily be seen that when using the device in the automatic mode, the physician need not press the manual reset button and therefore the device can be easily operated with one hand only. Use of the device in the automatic reset mode also appreciably reduces examination time.

Other pressure responsive means could be used for receiving and displaying the value indicative of the pressure applied to the body tissue provided the means has a known output characteristic which is constant in response to a constant or statically applied compressive force. Other means can be used to detect the variance in the electrical property, for example, a Wheatstone bridge can be used to determine the resistance of the pressure

responsive film. In addition, the member 16 can have other variable electrical properties dependent upon applied pressure. For example a member with a variable capacitance property is another possibility. Such a sensor can be formed by depositing thin conducting layers on both sides of a thin elastomeric substrate. A pressure applied to such material will change its thickness and therefore capacitance of the sensor. Changes of capacitance can be sensed by a variety of well known methods such as an AC bridge, or a variable frequency oscillator.

The member 16, and in particular the portion under the finger tip 32 is sized so as to permit substantial tactile communication to the physician's finger when touching an object, such as the joint of the patient's finger 14. In this preferred embodiment the tactile communication is achieved by making the film and the substrate relatively thin and flexible to accommodate the sense of the touch of the physician. It can be appreciated that the invention is not a substitute for the human finger tip, which is, by itself, a very sensitive diagnostic device. The invention fits adjacent the finger tip and does not interfere appreciably with the physician's ability to use the finger tip to determine with accuracy a precise location on body tissue where pressure is to be applied. The invention also permits the finger to apply pressure in a normal manner. In addition, the invention provides an accurate output of the actual applied pressure, and thus works in concert with the finger tip. The invention reduces or eliminates the need for the physician to try to ascertain, subjectively, the force applied to the joint by the finger tip. It is added that the invention permits the physician to detect many other tissue characteristics of the arthritic joint, such as tissue tension, tissue heat and consistency of the tissues of the joint being palpated, which are normally

detectable. The invention exhibits relatively high acuity and permits accurate reproduction of the applied force.

In another version of the invention, there is a communications ability between receiving and display apparatus 20 and a computer to record measured data. A short range telemetry link, such as an infrared beam similar to that used for T.V. controls, can be employed.

While specific embodiments of the invention have been described, such embodiments should not be considered as limiting the scope of the invention as construed in accordance with the accompanying claims.

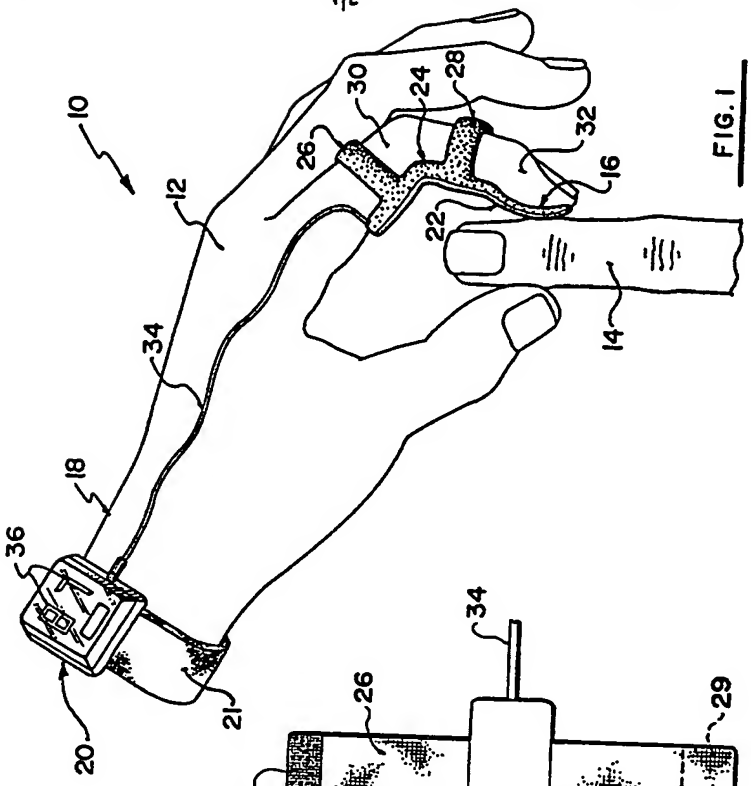
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FIG. 1

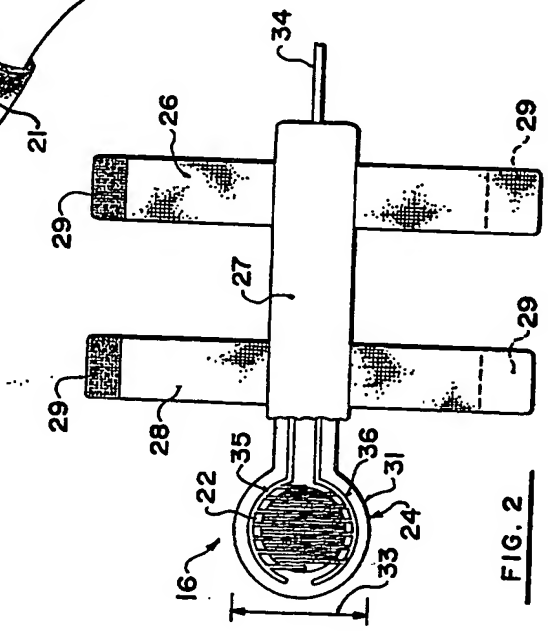
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FIG. 2

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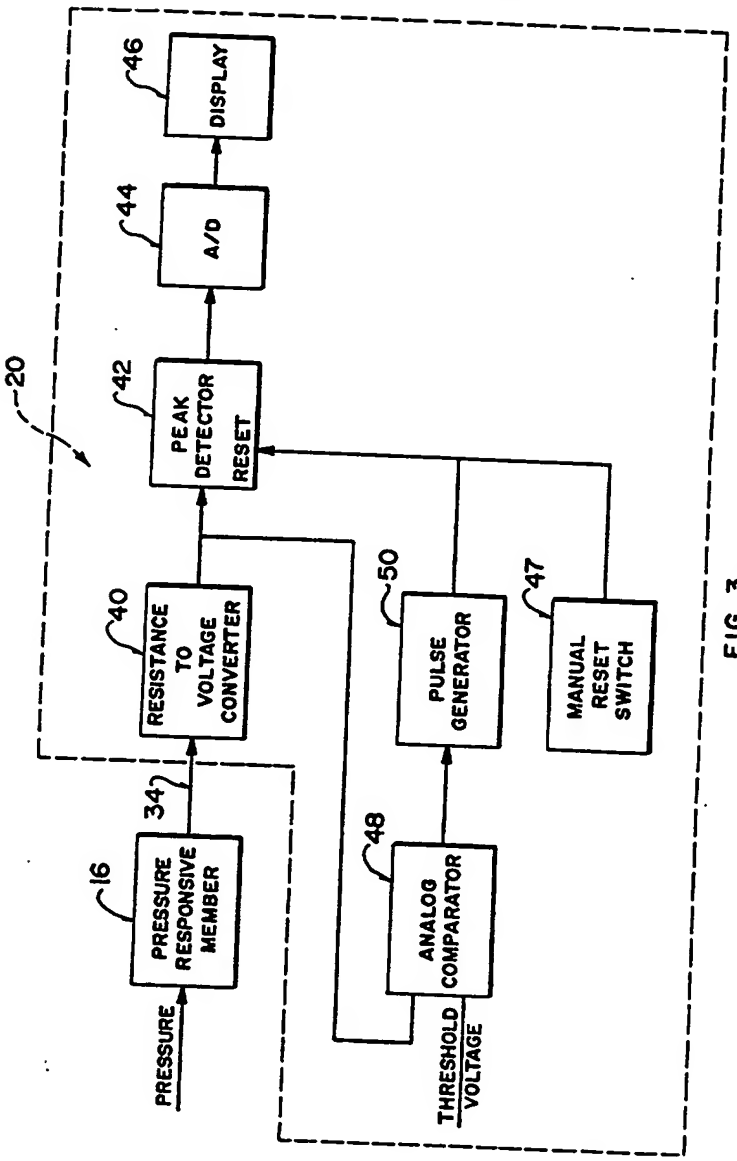
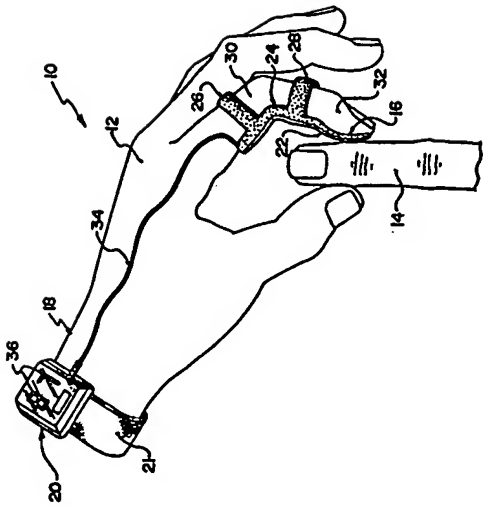


FIG. 3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